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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,853	06/13/2001	Amy H. Yin	AMCE-012/02US	8520
23419	7590	10/17/2003	EXAMINER	
COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,853

Applicant(s)

YIN ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-79 is/are pending in the application.
- 4a) Of the above claim(s) 13-40, 48-51 and 71-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 41-47 and 52-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1001.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group V, in a paper filed 7/08/03, without traverse, is acknowledged.

2. Claims 13-40, 48-51, and 71-79 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 41-47 and 52-70 are being acted upon.

3. Applicant is advised that the non-patent references filed in parent application no. 08/842,382 are unavailable to the Examiner. Accordingly, only the patent references on the Form 1449 filed 9/21/01 have been considered and initialed.

4. The specification is objected to for the following reason: the priority data in the first line of the specification must be updated. Applicant is advised that due to the Office's new electronic application format the Examiner no longer has access to the actual specification and can no longer make informal changes such as updating priority data or correcting minor errors such as mistakes in spelling. All such changes must now be made by formal amendment.

5. The declaration is objected to because it is unlikely that Inventor Miraglia actually signed said declaration in 1977. A new declaration is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 41-47 and 52-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In Claim 41, it is unclear why the claim begins with the word "In", the usage of which renders the claim ungrammatical. Additionally, the claim recites a "method of isolating hematopoietic stem cells". Accordingly, the claim must recite method steps that would result in an isolated cell. As currently recited, the claim comprises no actual steps that result in an isolated cell, thus the claim is vague and ambiguous.

B) In Claim 44, the abbreviation "aa" has not been defined. Accordingly the claim is vague and indefinite as the metes and

bounds of the method encompassed by the claim cannot be determined. Applicant is advised that the recitation of "amino acids (aa)" defining the abbreviation at its first usage would obviate the rejection.

C) In Claim 45, the recitation of "less than 10% crossreactivity" is vague and indefinite as the specification fails to define how said crossreactivity is determined. The specification merely discloses that any method might be employed, thus where one method might establish 9% crossreactivity with a given ligand/antigen, another method might establish 11% crossreactivity with the same combination. It would then be impossible to establish whether said ligand/antigen combination would be encompassed by the claims. Accordingly, the metes and bounds of the method encompassed by the claim cannot be determined.

D) In Claims 47, 55, and 65 the ATCC designation "HB12346" is used. Claim 47 indicates that the term refers to an antibody, whereas Claims 55 and 65 indicate that the term refers to a hybridoma. Accordingly, it is unclear just what "ATCC HB12346" is.

E) In Claims 60 and 70 a comma (,) appears between "cord" and "blood". This comma appears to be a typographical error. Additionally, the term "cytokine mobilized blood" has not been defined in the specification. Accordingly the claims are vague and indefinite as the metes and bounds of the method encompassed by the claims cannot be determined.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 41-47 and 52-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridoma HB12346 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. While it is noted in the specification that the hybridoma has been deposited

with the ATCC, it is unclear whether the deposit was made under the provisions of the Budapest Treaty. Accordingly, an affidavit or declaration to that effect is required. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, Applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Applicant's provision of these assurances through the submission of an appropriate declaration would obviate this rejection.

10. Claims 52-70 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the recitation of:

- A) "a mixed population of cells" (Claim 52) or, "a population of cells" (Claim 60).
- B) "cytokine mobilized blood" (Claims 60 and 70).

Applicant's amendment, filed 6/13/01, asserts that support for the new limitations can be found at various sites throughout the specification. However, support for the aforementioned specific limitations has not been found at pages 5, 6, 16, 17, or 38 as indicated.


11. No claim is allowed.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. **Please note:** any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
October 07, 2003



G.R. EWOLDT, PH.D.
PRIMARY EXAMINER